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K011149

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SMDA 510(k) SUMMARY

DISPOSABLE BENDING CANNULA PR-233Q

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: Of R&D Division, Endoscope Group	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	Disposable Bending Cannula PR-233Q
Common Name:	Disposable Cannula
Classification:	21 CFR 876.1500 Endoscope and accessories 21 CFR 876.5010 Biliary catheter and accessories
Predicate Device:	PR-23Q DISPOSABLE BALL TIP CANNULA K950729 KD-6G WIRE GUIDED PAPILLOTOMY KNIVES K950166

D. Description of the Device(s)

The subject device is a cannula which has a bending function (angle wire), to be used in accordance with Intended Use of the Device. This bending function enables the subject device to be manipulated in 2 directions and leads to easier insertion into the biliary and pancreatic ducts.

E. Intended Use of the Device(s)

The subject device, DISPOSABLE BENDING CANNULA PR-233Q has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, this subject device Disposable bending cannula PR-233Q does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Olympus Optical Co., LTD
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K011149
DISPOSABLE BENDING CANNULA PR-233Q
Dated: March 19, 2001
Received: April 16, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG
21 CFR §876.5010/Procode: 78 FGE

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number(if known): Not assigned yet K011149

Device Name: DISPOSABLE BENDING CANNULA PR-233Q

Indications for Use:

This instrument has been designed to be used with an Olympus endoscope to inject contrast medium in the biliary and pancreatic ducts, although it is not designed for the deep insertion into the pancreatic duct.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optoinal Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011149